CLRES 2050	Course coordinator:
Ethics and Regulation of Clinical Research	David Barnard, PhD

Course coordinator:

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Course objectives:

This course aims to provide an overview of the ethical and regulatory aspects of clinical research, with in-depth coverage of selected topics. Its objective is to familiarize course participants with the social and moral context for research with human subjects, the rationale for the current regulatory framework, and guidance in complying with ethical and regulatory requirements. The course is designed to fit into the larger context of the Clinical Research Training Program (CRTP). Participants who are engaged in other aspects of the CRTP will be able to apply what they are learning in this course to the work they are doing in other segments of the program. The final two sessions of the course, in the Spring, 2001, will provide the opportunity for detailed review and critique of Institutional Review Board protocols prepared in connection with research projects developed in the other sections of the CRTP.

Course requirements:

Attendance and participation in class discussions
Preparation of assigned readings
Preparation and critique of IRB protocol

Required textbook:

Robert J. Levine, *Ethics and Regulation of Clinical Research*, 2nd edition. (New Haven, CT: Yale University Press, 1988) is available for purchase. In addition to assigned chapters from this book, there will be occasional supplementary handouts.

Course mechanics:

1.5 credits; 24 contact hours; 12 sessions (2 hours each session)

Grading: H/S/U, based on participation

Location:

Room 1095 Biomedical Science Tower (BST), unless otherwise specified.

CLASS SESSIONS FOR INTENSIVE SUMMER SESSION

Session 1 — D. Barnard, PhD

July 12, 2000

Introduction and Overview

Session 2 — L. Parker, PhD

Aug 2, 2000 **995 BST**

Randomized Clinical Trials

Readings:

Levine, Chapter 8

Brody B., "The Use of Placebos in Clinical Trials," in Brody, Ethical Issues in Drug Testing, Approval, and Pricing. New York: Oxford University Press, 1995, pp. 112-24.

Concato, et al. Randomized, controlled trials, observational studies, and the hierarchy of research designs. NEJM, 2000, 342:1887-92.

Benson K, Hartz A. A comparison of observational studies and randomized controlled trials. NEJM, 2000, 342:1878-86.

Pocock SJ, Elbourne DR. Editorial: Randomized trials or observational tribulations. NEJM, 2000, 342:1907-09.

Session 3 — D. Barnard, PhD

Aug 9, 2000

Concepts, Principles and Moral Reasoning

Readings:

Levine, Chapters 1, 2, 3

Session 4 — D. Barnard, PhD

Aug 23, 2000

Informed Consent

Readings:

Levine, Chapter 5

CLASS SESSIONS – LONGITUDINAL COURSE – FALL AND SPRING*

**The readings for the fall & spring sessions were not available in time to include in this e-mail.*

Session 1 Recruitment of subjects

Topics:

1. Selection of the population to be studied
2. Under- and over-represented populations
3. Vulnerable populations

Session 2 Treatment of subjects

Topics:

1. Compensation and "undue inducement"
2. Compensation for injury
3. Privacy and confidentiality
4. Stopping rules

Session 3 Working with the IRB

Topics:

1. Mandate and authority
2. Procedures and process

Session 4 Compliance with federal rules and requirements

Topics:

1. Compliance with federal rules and requirements

Session 5 Responsible conduct of research

Topics:

1. Plagiarism
2. Falsification
3. Authorship
4. Whistle-blowing

Session 6 Conflicts of interest

Topics:

1. Role of investigator vs. role of treating physician
2. Relationships to sponsors
3. Ownership of data and freedom to publish

Session 7 Review and critique of participant protocols

Topics:

1. Review and critique of participant protocols

Session 8 Review and critique of participant protocols

Topics:

1. Review and critique of participant protocols

Bibliography

Bulger, RE, Heitman, E., and Reiser, SJ. The Ethical Dimensions of the Biological Sciences. New York: Cambridge University Press, 1993.

Levine, RJ. Ethics and Regulation of Clinical Research. New Haven: Yale University Press, 1988.

Vanderpool, HY. The Ethics of Research Involving Human Subjects: Facing the 21st Century. Frederick, MD: University Publishing Group, 1996.

And relevant articles from the medical literature.